UNITED STATES DISTRICT COURT DISTRICT OF NEVADA

BAYER SCHERING PHARMA AG, et al.,

Plaintiffs,

v.

WATSON PHARMACEUTICALS, INC., et al.,

Defendants.

Case No. 2:07-CV01472-KJD-GWF

<u>ORDER</u>

Presently before the Court is Plaintiffs' Motion for Summary Judgment of Infringement (#183/185). Defendants filed a Joint Opposition (#200) in response and a Cross-motion for Summary Judgment of Non-Infringement (#202). Plaintiffs ("Bayer") filed Consolidated Reply in Support of their Motion for Summary Judgment (#213) and Opposition (#215) to the cross-motion for summary judgment. Defendants filed a Reply (#223) in support of their cross-motion.

22 I. Background and Analysis

This action was filed on November 5, 2007. On September 4, 2008, Bayer and Defendant Watson Pharmaceuticals, Inc. ("Watson") filed a stipulated Joint Proposed Claim Construction (#42)("the Stipulation"). On November 4, 2008, the Court consolidated 2:08-cv-0995-RLH-RJJ

¹It appears that this evidence was derived from "an opposition proceeding" before the European Patent Office

("EPO") and was filed in that action on October 23, 2009 and possibly December 10, 2009.

with this action, essentially adding Defendant Sandoz, Inc. as a party. Sandoz later agreed to be bound by the stipulated claim construction.

On June 28, 2010, Bayer filed the present motion for summary judgment asserting that there is no evidence to dispute that Defendants infringed its U.S. Reissue Patent Nos. 37,564 ("the '564 patent") and 37,838 ("the '838 patent"). Defendants do not dispute that their New Drug Applications ("NDAs") which caused the initiation of this lawsuit infringe the '564 patent and acquiesce to the granting of Bayers' motion for summary judgment of infringement of this patent. However, Defendants do dispute infringement of the '838 patent.

For the first time in this action, on August 12, 2010, Defendants asserted to the Court that they dispute the claim construction contained in the Stipulation. Particularly, Defendants now dispute the construction of the claim term "drospirenone which is equivalent to 75 µg of gestodene" as being "[b]etween 2 and 4 mg of drospirenone."

From the initial briefing it appears that "newly" discovered evidence affects the analysis of the patent claims in this action. On October 23, 2009, Bayer, in its Statement of Ground of Appeal in the EPO proceeding, stated that to a person of ordinary skill in the art, "a dose of drospirenone being equivalent to 0.075 mg gestodene would be about 3.75 mg." Bayer also submitted the statement of Professor Thomas Rabe, MD, in support of its appeal on or about December 10, 2009. Rabe's statement explained that a person skilled in the art would have conducted "absolutely standard" calculations to determine what an equivalent dose of drospirenone would be to that of 0.075 mg of gestodene. Rabe concluded that based on the rule of proportions "an equivalent dosage of drospirenone [to 75 µg of gestodene] is also 1.9 times higher than its threshold dosage (2 mg), i.e about 3.75 mg."

Since the new proposed construction would place the amount of drospirenone outside the range of drospirenone in Defendants' ANDAs, this construction would be dispositive of Bayer's

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infringement claim. The construction of patent claims is a question of law for the Court to decide. Markman v. Westview Instruments, Inc., 52 F.3d 967, 978–81, 987 (Fed. Cir. 995). It is within the Court's discretion whether to hold the parties to the previous stipulation or to revisit and change the claim construction during the course of the action.

The Federal Circuit however, has held that Markman "does not require a district court to follow any particular procedure in conducting claim construction." Ballard Medical Products v.

Allegiance Healthcare Corp., 268 F.3d 1352, 1358 (Fed. Cir. 2001). The Ballard opinion specifically recognized that district courts have "wide latitude" in how they conduct claim construction, and that "there is nothing unique about claim construction that requires a court to proceed according to any particular protocol. As long as the trial court construes the claims to the extent necessary to determine whether the accused device infringes, the court may approach the task in any way that it deems best." Id.

Accordingly, the Court denies the motions for summary judgment without prejudice. The Court desires further briefing on the claim construction at issue here. Particularly, the Court wants briefing specific to the range of Rabe's statement that the equivalent amount is "about 3.75 mg" (emphasis added). The parties should further address when extrinsic evidence may be considered in addition to intrinsic evidence. Finally, each party should address whether oral argument and presentation of evidence would aid in claim construction, or whether the issue can be decided on the briefing of the parties.

Therefore, Plaintiff is ordered to file its opening brief within thirty (30) days of the entry of this order. Defendant shall file a reply within twenty-one (21) days of the filing of the opening brief to which Plaintiff shall respond within fourteen (14) days. The Court will set a hearing or rule on the claim construction within thirty (30) days of completion of the briefing.

II. Conclusion

Accordingly, IT IS HEREBY ORDERED that Plaintiffs' Motion for Summary Judgment of Infringement (#183/185) is **GRANTED in part and DENIED in part**;

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1	Plaintiffs' Motion for Summary Judgement for Infringement is GRANTED as to the '564
2	patent;
3	Plaintiffs' Motion for Summary Judgement for Infringement is DENIED as to the '838
4	patent;
5	IT IS FURTHER ORDERED that Cross-motion for Summary Judgment of Non-Infringement
6	(#202) is DENIED without prejudice .
7	DATED this 31 st day of March 2011.
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11	Kent J. Dawson United States District Judge
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